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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,192	06/16/2005	Gordon Feingold	09138.0074	2551

63432 7590 03/14/2011
DAKO/FINNEGAN, HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1773

MAIL DATE	DELIVERY MODE
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03/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,192	Applicant(s) FEINGOLD ET AL.	
	Examiner Brian R. Gordon	Art Unit 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 358-365, 367-378 and 380-385 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 358-365, 367-378 and 380-385 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 28, 2011 has been entered.

Response to Arguments

2. Applicant's arguments filed February 28, 2011 have been fully considered but they are not persuasive.

Instead of providing a specific location for the support and amending the claims to include language consistent with the specification, applicant asserts the steps of sending commands and/or queries over the network are inherently disclosed throughout the specification. The examiner disagrees. Applicant is only entitled to what is disclosed in the specification. While numerous uses of network may be known and considered obvious that does not entitle applicant to assert any all obvious uses of networks are inherently disclosed in the application because applicant has disclosed a network. While it may be known that data may be transmitted over a network, here applicant is claiming a step that requires specific data (commands and queries) to be transmitted over the network. The examiner fails to locate the terms "commands" and "queries" or any variation thereof with in the specification. The examiner suggests applicant employ

claim language and terms that are consistent with that employed within the specification. If applicant wishes to maintain the same language and disagrees with the examiner, the examiner requests applicant provide the specific text of the original specification that supports the claimed steps.

The inserting a reagent or sample without interrupting step is not supported in the specified passages as asserted. Page 9, lines 9-20, is directed to Figure 1 and use of the indicator elements 112 to indicate the status and accessibility of drawers. . . . There is no mention of inserting a second sample or reagent without interrupting processing of a first sample as claimed. Page 24, lines 18-25, discusses the introduction of slide retainment assemblies and reagent containers into drawers. The passage also discusses scheduling for sample loading, but it does not state anything about a second sample or reagent being inserted without interruption of processing a first sample as claimed. Page 28, lines 20-24, makes a general statement about sample and slide insertion and removal. The passage does not describe the claimed insertion step.

Applicant asserts storing information about a slide of same is disclosed at page 21, lines 20-35. It is unclear what specific claim or steps applicant is referring to. If applicant is referring to claims directed to the laboratory information system (LIS) (361-362 or any others), the reference passage does not mention the LIS or any information as claimed being stored therein. The referenced passage is directed to slide identification information which is not listed in the claims and not described as being related to a LIS as claimed. The only mention of an LIS is on page 26, line 24. (last line of paragraph 0075 in applicant's publication US 20060088940). If applicant is

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attempting to refer to the log files that may be generated as described in the bridging paragraph of pages 26-27, it is suggested applicant amend the claims to be consistent with such.

As to the database maintenance/diagnostic tests, paragraphs 0075-0076 states both may be accomplished manually or automatically and maybe communicated over various links. However, there passages do not state neither is derived from and stored as commands and queries in a LIS as stated in claims (363-364, 375).

It is unclear what specific steps applicant is asserting is supported by page 10, line 33. However, the passage merely mentions an information monitor 402 use to notify a person. There is no mention of the specific steps of the claims such as retrieving diagnostic information from a database and electronically notifying an operator about the results.

Applicant directs the examiner's attention to page 17, line 32. It is unclear if applicant is attempting to assert that this line supports the step of a computer providing real time completion time estimate of the first sample. If so, the examiner disagrees. There's no mention of a computer, a first sample, or a stainer within the passage. Does applicant consider an estimated temporal impact to be the same as a completion time estimate? The examiner does not agree that the passage supports the step recited in the claim. If applicant referring to an action/step related to the temporal estimate, applicant should amend the claim to clarify such by employing language consistent with the specific passage. It should be noted, however that the examiner does notice the reference to a real time completion estimate element (paragraph 0059), but it is not

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described relative to any sample and the capture of historical information (paragraph 0063).

While applicant has referenced specific portions of the specification, applicant has not provided for where each and every claim (all the steps) is supported in the original specification.

The examiner fails to locate the disclosure of a robotic head. No robotic head is described in the specification. However, if applicant is referring to the staining apparatus 201 comprising a XY movable robotic arm that positions a probe 210 mounted on the robotic arm, applicant should amend the claims to clearly indicate such.

As to claims 360 and 374, the examiner fails to locate support for a server comprising a centralized database including stainer configuration information.

As to claims 365, 368, 378, and 382, while the specification does disclose automatic diagnostic operations, the examiner fails to locate where the specification states diagnostics are specifically performed on any stainer; the diagnosis on a stainer is performed while operation other stainers in the stainer network, and how the other stainers are or are not affected by the diagnostic operations. Where is disclosed in the specification?

The examiner fails to locate support for the computer monitoring steps as claimed. However, system monitoring is disclosed in paragraphs 0044-0045, and 0047.

As to claim 376, the examiner fails to locate the term malfunction or any variation thereof. Where are the claimed steps disclosed in the specification?

As to claims 371 and 385, the examiner fails to locate support for the step of sending encrypted commands and queries.

For reasons above, the examiner maintains the position that the claims are directed to new matter.

The examiner agrees that the claim does require a step of inserting a second sample into the stainer and insertion of at least one reagent is optional. As such, the previous rejections based upon Lemme are hereby withdrawn.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Interpretations

4. The term "stainer" has not been defined or restricted to a specific structure. Any device capable of dispensing fluids to slides or any other objects/substrates can be considered a stainer.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 358-365, 367-378, and 380-385 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

. While it is claimed that the processing occurs with the robotic head it is not specified where the processing of the first sample occurs. The claim does not preclude the robotic head from having the ability to move or extend beyond the boundaries of what applicant considers as the stainer. Thus, processing with the stainer is not the same as processing in the stainer. It is conventionally known the robotic arms/heads can have wide ranges of motion. As such, it is foreseeable that the robotic head is not limited to movement and being operated in the at least one stainer.

Therefore, it appears as if the claims should include a step of inserting a first sample in the stainer prior to the processing step.

As to claim 362 and 372, it is unclear what is the relative location of the "a database" to the previously mentioned elements. Where is the database located? Is it a separate hardware component connected to the network or a software component stored in the server, stainer, etc. It is unclear if the database is the same as the centralized database of claim 360.

As to claims 363 and 375, it is unclear if the operations are pertaining to the database mentioned in claims 362 and 372, respectively or a different database.

Claim 364 recites the limitation "the database" in the last line. There is insufficient antecedent basis for this limitation in the claim.

As to claims 364-365, 377-378 it is unclear who or what runs the diagnostic tests and receives the diagnostic information.

As to claims 364 and 377, it is unclear what is meant by retrieving diagnostic information. Does this mean results are sent to a specific location (such as computer, display, printer, etc.)? Does this mean an operator manually records results? Does this mean an operator gathers information for running the tests? Does this mean a computer or other device communicates with some other device/database and electronically collects the information from there? How is the user provided information? A user can receive information by mere observing the device with one's eyes (looking at the structural components).

As to claim 365 and 378, it is unclear what is meant by "actively exercise components". It should be noted that no prior claims require or state the stainer has any specific components on it. It is unclear what are the components of the stainer. The only specific component that could be reasonably interpreted is the robotic head. However as previous stated the phrase "coupled to the stainer" does not require the robotic head to be an element of the stainer. The claims do establish/positively claim the stainer as comprising and specific components. As such, it is unclear what components are exercised.

It should be noted that the steps of claims 368, 371, 382, and 385 are not restricted be performed by any specific device or structure. An operator can perform these steps (operations) by observing with one's own eyes, mentally. One can

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troubleshoot, monitor, encrypting, and estimate within ones own mind. Mental, abstract steps are not patentable.

As to claim 376, it is unclear where the second stainer is located. Where is the second stainer provided? Is it connected to the network? The broad term "providing" does not require the second stainer to be connected to the network. It has not been established that a second stainer is included in the structure required for the method.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 358-365, 367-378, and 379-385 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See Response to Arguments.

Applicant has amended the claims, but failed to specify where the amendments are supported within the specification. The examiner fails to locate where the invention as claimed as located and more specifically the amendments. It is hereby requested applicant specify text of originally filed specification that provides support for each and every claim.

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Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 358-365 are rejected under 35 U.S.C. 102(e) and (a) as being anticipated by Feingold, Gordon Allen et al., US 7, 603,201 (assuming this is the same inventor Gordon Feingold of the instant application).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The Feingold et al. reference fully encompasses the scope of the instant claimed invention. Feingold et al. discloses a method of operating slide stainer 1000 that includes a robot head 1010 for staining/processing (dispensing reagents to) slides 1045. The reference states: [o]nce the processing of loaded slides 1045 has been completed, in step 1135, slides 1045 and reagent bottles 1080 may be unloaded. In some embodiments, reagent bottles 1080 may be swapped and/or new reagents added while

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slides 1045 are being processed. In some embodiments, new slides 1045 may be introduced for processing in a slide drawer 1040 that is currently unused, or reagent bottles 1080 introduced and/of removed, while slides 1045 in another slide drawer 1040 are being processed. Processing on such new slides 1045 introduced into stainer 1000 may begin even while processing on other slides previously presented to the stainer is in progress. In some embodiments, steps 1120 through 1135 may be repeated until all slides 1045 have been processed. (column 14, lines 12-24).

In some embodiments, establishing a network connection with the at least one stainer in the LAN further comprises establishing a network connection with an agent within the LAN, wherein the functions of the agent comprise relaying commands to, and responses from the at least one stainer, and relaying queries to, and returning responses from, a database associated with the plurality of stainers, wherein the database includes information including status information about stainers, slides, consumables, and treatment protocols associated with the plurality of stainers. In some embodiments, the agent is a software tool that also provides a defined interface for an external application through which operations may be performed on the at least one stainer over the network. In some embodiments, the external application is a laboratory information system (LIS 1222). (beginning at column 7, line 36).

The reference further discloses a server comprising a centralized database.
(claim 7).

Stainer-server communications may also include database update (maintenance operations) requests and/or commands, such as remove reagent rack; reject slide rack.

. . .

In some embodiments, SMS 1320 may have a backup and restore utility that can allow for automatic backups on a user-specified, predetermined, or default schedule. (see also claim 10).

In some embodiments, the operations performed over the network on the at least one stainer include running diagnostic tests and retrieving diagnostic information. In some embodiments, the diagnostic information is used to automatically schedule service on the at least one stainer, if the diagnostic information indicates that such service is to be performed. (column 8, lines 2-9).

In some embodiments, the operations performed over the network on the at least one stainer include monitoring the status of slides being processed by the at least one stainer apparatus. In some embodiments, the operations performed over the network on the at least one stainer include obtaining a real-time estimate of the completion time of any of the slides being processed by the at least one stainer. (column 8, lines 31-42).

In some embodiments, all information exchanged with the stainer over the network connection, including all commands sent to the stainer over the network connection and all responses received over the network connection, are encrypted. (column 8, lines 51-55).

10. Claims 358-360, 369, 372, 381, and 383 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalra et al., US 6,495,106.

Kalra et al. disclose an automated staining apparatus comprising a robotic head 70 that dispenses reagents to slides 130 contained within slide trays 190. A gap 198 is present at one end of well 192 to allow easy grasping of an individual microscope slide 130 between thumb and forefinger for insertion into and removal from tray 190. Furthermore each of the trays include tabs that allow for each of the trays to be removed without disturbing dispensing to other slides in other trays. One benefit of this batch processing strategy is that the apparatus can process trays of slides in a manner which completes the prescribed processing on a single tray 190, and then signal the user to remove the tray and replace it with a fresh tray, without interrupting the processing of the remaining trays. In this manner, the apparatus can be utilized continuously with a minimum of intervention by the user. (column 17, lines 54-61).

The control means of the apparatus 10 could monitor the volume of reagent remaining in each reagent vial 110, and arrange for disposal and replacement of the vial 110 and pipette tip 90 as appropriate. (column 12, lines 37-40).

In an `open` format, for a typical operation, a user would be asked to select the location and volume of the reagents, the location of the slides being treated, and the length of time for various steps such as incubation times; all other operations can be carried out by the pre-programmed instruction set in the memory of the computer, which will control actual movement of the movable arm to the appropriate locations and activation of the various gas and liquid control systems. In a `closed` format, bar-code

technology can be used to supply instructions to the apparatus. The apparatus reads bar-codes associated with both the reagent vials 110 and the slides 130; thereafter the computer is able to determine all parameters needed to carry out the most appropriate pre-programmed instruction set in the memory of the computer to control the apparatus in the processing procedures for microscope slide staining. Compared with the `open` format, less user input is required, thus reducing the opportunities for introduction of error. (beginning at column 18, line 52).

The device is connected to and controlled by a computer or other programmable control device (network). (column 18, lines 31-52).

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 361-365, 367-368, 370-371, 373-378, 380, 382, and 384-385 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalra et al., US 6,495,106 as applied above in view of Lemme et al. US 2002/0110494 A1.

Kalra does not disclose multiple stainers are included in the network.

Lemme et al. disclose a method and apparatus for an automated biological reaction system. In the processing of a biological reaction system, there is a need for consistently placing an amount of fluid on a slide. In order to operate the automated biological reaction system more reliably, the system is designed in modular pieces with higher functions performed by a host device and the execution of the staining operations performed by remote devices. Also, to reliably catalog data which is used by

the automated biological reaction system, data is loaded to a memory device, which in turn is used by the operator to update the operator's databases. The generation of the sequence of steps for the automated biological reaction device based on data loaded by the operator, including checks to determine the ability to complete the run. (Abstract).

FIG. 5A, shows a block diagram of the automated biological reaction system 150. The automated biological reaction system 150 is segmented into a host device 32 (server), which includes a typical personal computer, and at least one remote device 166, which includes the automated biological reaction device in FIGS. 2 and 6A. In the preferred embodiment, there are up to eight remote devices 166 which communicate with the host device 32. Each remote device 166 on the network has a unique address so that each remote device 166 may be identified and individually controlled by the host device 32. As described subsequently in FIG. 5B, the automated biological reaction system 150 can support up to eight remote devices 166 due to the 3 bits (values 0-7) dedicated to the addressing of the remote devices 166. A rotary switch is provided on the remote device 166 to allow for the identification and the changing of the 3 bit address for each remote device 166. All host messages include this address in them, as described subsequently in FIG. 5B. However, the number of remote devices 166 can be smaller or larger than eight, depending on the capacity requirements or practical limitations of the laboratory in terms of space. Moreover, the remote devices 166 may be immunohistochemistry staining modules, another type of instrument that performs a different type of staining, or another type of medical testing device. (paragraph 105).

Communication between the host device 32 and the remote devices 166 is accomplished using a serial RS-485 link, which serves as a network, that supports one host and up to 32 remotes at one time. In the preferred embodiment, addressing of the remote devices 166 allows up to 8 remote devices to communicate with the host at one time. The RS-485 link has at least two pairs of lines for communication, one pair for transmitting and one pair for receiving. The remote devices 166 which are connected to the network "hear" the host messages but do not "hear" other remote messages. In the preferred embodiment, all communications begin with a host message, followed a short time later by a response by a remote device 166 if present. (sending/receiving) If the host device 32 sends a message and there is no remote device 166 to respond to it, the host device 32 times out. In this manner, the communication provides a simple, collision-free link between the host device 32 and the remote devices 166. In an alternative embodiment, the remote devices 166, in addition to communicating with the host device 32, address each other. For example, the remote devices 166 address each other using the unique 3 bit address, sending information about staining runs, which are described subsequently. (paragraph 106).

The user database, which is required by the regulations, contains various tables including the registration, receive and quality control tables for use by the operator. Within each of the registration, receive and quality control tables, there are five different types of categories: (1) antibodies; (2) reagents; (3) kits; (4) consumables, and (5) control slides. (paragraph 226).

The claims do not appear to claim any novel aspects of the use of computer networks. Computer networks are staple components of today's society. It is readily known that WAN and LAN networks are employed for sending various types of data (including encrypted, i.e. internet or intranets) in various environments ranging from private homes, businesses, hospitals (see paragraph 240), laboratories, etc. The use of networking and backup hardware/software is inherent in a network configuration such as that taught by Lemme et al. (see also Showalter, provisional application 60/487,998, prior art submitted by applicant).

It would have been obvious to one ordinary skill in the art at the time of the invention to recognize multiple stainers maybe included in the network as taught by Lemme et al. to allow or remote operation of the stainers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
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